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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Kobrehel, et al. Art Unit: 123

Serial No.: 304,481 Examiner: Chan

Filed: September 22, 1981

For: NEW ERYTHROMYCIN A COMPOUNDS, A PROCESS FOR THE MANUFACTURE THEREOF AND THE USE OF THE NEW COMPOUNDS IN THE CONTROL OF BACTERIA

dated

REPLY BRIEF

606-82

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is a reply to the Examiner's Answer dated August 9, 1984.

REMARKS

The Examiner's conclusion on page 3, lines 1-3 of the Examiner's Answer that U.S. Patent 4,328,334 to Kobrehel, et al. renders the compounds of the rejected claims prima facie obvious is not tenable and is not supported from a review of U.S. Patent 4,328,334 taken as a whole. In particular, since U.S. Patent 4,328,334 discloses that R_1 is H, acyl, or 4-R-C_6H_4-SO_2 (wherein R is alkyl, halogen, or acylamino), said patent actually leads away from the present invention which employs the simple methyl group as compared to the more sophisticated substituents acyl and 4-R-C_6H_4-SO_2 when the H is substituted. If the substitution of H with a simple CH_3 were an obvious substitution to provide active compounds, then surely the patentee would have suggested such at least

in addition to the more complex and sophisticated substituents of aryl and 4-R-C_6H_4-SO_2 disclosed therein. In fact, it was not obvious to replace the amine hydrogen of the reference with methyl since the pharmaceutical properties could not be predicted from the chemical structure.

The Examiner has also criticized the comparative showings provided by applicant because of an absence of a comparison of the cyclic carbonate of the claimed N-methyl compound with the cyclic carbonate of the reference. However, no additional information is required for such a comparison since the minimum inhibitory concentrations (MIC) in mcg/ml for the 13,14-cyclic carbonate of 11-aza-10-deoxo-10-dihydroerythromycin A were given in Table 1 and its acid stability in Table 3 of the cited U.S. Patent 4,328,334 to Kobrehel, et al. This 13,14-cyclic carbonate of the unsubstituted nitrogen compound was designated as compound VI in Tables 1 and 3 and its manufacture was disclosed in Example 10 of the cited patent.

The minimum inhibitory concentrations and the acid stability of the claimed 13,14-cyclic carbonate of N-methyl-11-aza-10-deoxo-10-dihydroerythromycin A (Claim 7) are given in Table 2 and Table 7 respective of the present application.

The comparison of the data given for each cyclic carbonate shows the superior properties of the claimed 13,14-cyclic carbonate of N-methyl-11-aza-10-deoxo-10-dihydroerythromycin A.

Accordingly, this data clearly establishes patentability of at least claim 7.

In view of the above and in view of our Appeal Brief, it is submitted that the Examiner erred in the final rejection of claims 3-11 and accordingly, it is requested that the Board

of Appeals reverse the Examiner.

Respectfully submitted,

Date: 8-24-84

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